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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,752	12/06/2005	Andre Lieber	016336-002700US	5845

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EXAMINER	
BLUMEL, BENJAMIN P	
ART UNIT	**PAPER NUMBER**
1648	

MAIL DATE	DELIVERY MODE
09/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/559,752	LIEBER ET AL.	
	Examiner	Art Unit	
	Benjamin P. Blumel	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *December 6, 2005*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-52* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

BC 8/30/17

Group I, claim(s) ~~1-39~~ 1-31, 33-39, drawn to a recombinant adenovirus fiber protein, the nucleic acid the encodes the recombinant protein and a cell that contains the nucleic acid.

Group II, claim(s) 32, drawn to a method for producing adenovirus.

Group III, claim(s) 40, drawn to a method of making a medicament.

Group IV, claim(s) 41-52, drawn to a method of administering an adenoviral vector.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The inventions of Groups I-IV lack an inventive step under PCT Article 33(3) as being obvious over Koizumi et al. (The Journal of Gene Medicine, 2003) and Shayakhmetov et al. (Molecular Therapy, 2003). The claimed inventions are drawn to a chimeric adenovirus fiber protein with a mutation of a blood factor binding site that reduces its affinity, the nucleic acid encoding the protein, a cell containing the nucleic acid, an adenovirus containing a chimeric fiber protein, a cell containing the recombinant adenovirus, methods of producing and administering the adenovirus and pharmaceutical compositions comprising the nucleic acids, the adenovirus, and the adenovirus infected host cell. Koizumi et al. teach

adenovirus 5 (Ad5) with mutated fiber proteins that contain heterologous nucleic acid sequences inserted into the fiber knob. Mammalian cells were utilized in producing recombinant adenovirus vectors. However, Koizumi et al. do not specifically teach the expression of a blood related factor being inserted into the adenovirus fiber knob region. Shayakhmetov et al. teach adenovirus expressing a Factor IX that is inserted into the knob region of the virus and increases viral infectivity while reducing binding and therefore toxicity. Therefore, given the teachings of Koizumi et al., one skilled in the art would be motivated to produce a chimeric adenovirus that contains a blood related factor located in the fiber knob of the virus and employing this chimeric virus in gene therapy regimens. Because the invention of claim 1 lacks an inventive step, the shared technical feature which the groups have in common is not a special technical feature within the meaning of PCT rule 13.2.

Election of Species

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

If invention I is elected, an election of a specific species from each group stated below is also required.

A. A specific blood factor protein as stated in claim 2.

B. A specific gene as stated in claim 20.

C. A specific mutated region as stated in claims 4, 8, 10 and 12.

D. A specific adenovirus fiber as stated in claims 7, 9 and 11.

If invention II is elected, an election of a specific species from each group stated below is also required.

E. A specific deletion and gene as stated in claims 29 and 30.

No matter which invention is elected, a specific species from each group stated below is also required.

F. A specific ligand as stated in claims 16, 24, 44 and 51.

G. A specific insertion site as stated in claims 17 and 25-27.

H. A specific recombinant adenovirus as stated in claims 28 and 38.

I. A specific gene as stated in claims 31, 36, 39, 45 and 52.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

A. Claim 2 requires a specific blood factor protein, all other claims are generic.

B. Claim 20 requires a specific gene, all other claims are generic.

C. Claims 4, 8, 10 and 12 require a specific mutated region, all other claims are generic.

D. Claims 7, 9 and 11 require a specific adenovirus fiber, all other claims are generic.

E. Claims 29 and 20 require a specific deletion and gene, all other claims are generic.

F. Claims 16, 24, 44 and 51 require a specific ligand, all other claims are generic.

G. Claims 17 and 25-27 require a specific insertion site, all other claims are generic.

H. Claims 28 and 38 require a specific recombinant adenovirus, all other claims are generic.

I. Claims 31, 36, 39, 45 and 52 require a specific gene, all other claims are generic.

The following claim(s) are generic: all claims are generic.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each gene, blood factor protein, mutation, adenovirus fiber protein, gene mutation, ligand, insertion site and adenovirus are distinct species since each varies between it and the other claimed species based on chemical, physical and functional properties. For example, the blood factor proteins of claim 2 function in distinct ways, have different compositions and share no homology.

Summary

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin P. Blumel whose telephone number is 571-272-4960. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin P Blumel/
Examiner
Art Unit 1648

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